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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,504	01/22/2002	Ralph Leonard		4759

7590 02/15/2006

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EXAMINER	
BLECK, CAROLYN M	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,504	LEONARD ET AL.	
	Examiner	Art Unit	
	Carolyn M. Bleck	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed on 22 January 2002. Claims 1-20 are pending. An IDS has not been filed with this application.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

3. It is noted that the Examiner cited the references in form PTO-892.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

5. The oath or declaration is defective because:

> It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data

sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration.

6. It is noted that Applicant filed a "Declaration for Utility or Design Application using an Application Data Sheet" on 22 January 2002. However, an Application Data Sheet was never filed with the application.

Specification

7. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

9. The abstract of the disclosure is objected to because the abstract describes the purported merits or applications of the invention and compares the invention to the prior art. See lines 1-5 of the Abstract. The abstract is also objected to because it uses phrases which can be implied such as "We describe." Correction is requested. See MPEP § 608.01(b).

Claim Objections

10. Claim 1, lines 1-2, is objected to because of the following informalities: it appears that the recitation of "to each combination of medical conditions the risks and benefits" is grammatically incorrect. Claim 3, line 5, "be cause appears to be grammatically incorrect. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-20 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claims are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device or system/apparatus must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claims must be in one sentence form only. Note the format of the claims in the patents cited. See US 5,594,637 (Eisenberg et al.), 6,128,620 (Pissanos et al.), 6,334,192 (Karpf), 6,458,080 (Brown et al.), 6,529,892 (Lambert), 6,789,091 (Gogolak), 6,804,661 (Cook), and 6,826,541 (Johnston et al.).

(A) Claim 1 recites "The systematic process of assigning a quantitative score to each combination of medical conditions the risks and benefits (indications and contraindications, respectively) of all relevant pharmaceutical and non-pharmaceutical classes of therapies for a given disease process described above as Selection of Optimal Medication Methodology." Claim 1 then recites a series of sub-claims A-C.

First, it is unclear what statutory class of invention claim 1 belongs to because the claim appears to recite a process, yet the sub-claims recite a SOOMM system. A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph, because it is unclear

which category of invention is being claimed. Such a claim "is not sufficiently precise to provide competitors with an accurate determination of the 'metes and bounds' of protection involved" and is "ambiguous and properly rejected" under section 112, paragraph 2." *Ex parte Lyell,* 17 USPQ2d 1548, 1550-51 (BPAI 1990). In addition, claims 2-20 recite either an SOOMM system or an SOOMM process. Because it is unclear what statutory class of invention claim 1 belongs to (i.e., a system or process), it is entirely unclear whether claims 2-20 should recite a system or a process. For example, claim 2 recites "the SOOMM system" whereas claim 3 recites "the SOOMM process." Thus, it appears claims 1-20 recite both a system and a process, and thus it is unclear which statutory class of invention is being claimed.

Second, it is unclear whether sub-claims A-C are part of independent claim 1 or are claims which depend on claim 1. Claim 1 and sub-claims A-C recite multiple sentences. However, claims must be in one sentence form only. Note the format of claims in the patent(s) cited. See US 5,594,637 (Eisenberg et al.), 6,128,620 (Pissanos et al.), 6,334,192 (Karpf), 6,458,080 (Brown et al.), 6,529,892 (Lambert), 6,789,091 (Gogolak), 6,804,661 (Cook), and 6,826,541 (Johnston et al.).

Third, claim 1, sub-claims A and B recite language such as "may use" or "may be." It is unclear whether these sub-claims are required by claim 1 or are optional steps limitations. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.

Fourth, claim 1 recites a systematic process of "assigning a quantitative score to each combination of medical conditions the risks and benefits (indications and contraindications, respectively) of all relevant pharmaceutical and non-pharmaceutical classes of therapies for a given disease." The Examiner respectfully submits that it is unclear what the relevant pharmaceutical and non-pharmaceutical classes of therapies are for a given disease. How are these classes of therapies determined? What makes the particular classes relevant to a given disease?

Regarding claim 1, the phrases "indications and contraindications, respectively" at lines 2-3, "but the suggested system" at line 7, "e.g., as proposed by the FDA" at line 12, and "but also based on de novo schemes" at lines 12-13 render the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is also unclear what "de novo schemes" would include.

Fifth, claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language "a given disease process described above." This claim is an omnibus type claim.

Last, claim 1, line 4 "given disease process described above" lacks proper antecedent basis. Claim 1, line 5, 9, 14, "the SOOMM system" lacks proper antecedent basis. It is unclear to the Examiner where an SOOMM system is described within claim 1.

Claims 2-20 incorporate the deficiencies of claim 1 through dependency, and are therefore rejected as well.

(B) It is unclear whether claims 2-20 depend on independent claim 1 or are independent claims. For example, claim 2 recites that "the SOOMM system may be further augmented by additional external rules." It appears this claim is attempting to further limit claim 1. It is respectfully submitted that Applicant review the cited patents which provide examples of the format of independent and dependent claims. In addition, claims must be in one sentence form only. Claims 3, 5, 6, 15, and 16 recite multiple sentences. See US 5,594,637 (Eisenberg et al.), 6,128,620 (Pissanos et al.), 6,334,192 (Karpf), 6,458,080 (Brown et al.), 6,529,892 (Lambert), 6,789,091 (Gogolak), 6,804,661 (Cook), and 6,826,541 (Johnston et al.).

(C) Claims 2-20 recite language such as "may use," "may be," "could be," and "can also be." It is unclear whether these limitations are required or are optional steps limitations. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.

(D) Regarding claims 4-5, 7, and 20, the phrases e.g., i.e., and etc. render the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 6, 8, and 12, the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

(E) As per claim 2, it is unclear to the Examiner what the recitation within claim 2 of "all other things being equal" means. What other things are being kept equal?

(F) As per claim 3, it is unclear to the Examiner how the best therapeutic class is chosen. What is the "best" therapeutic class? What selection criteria are used to select the best class? It is unclear what "9-cell model is illustrated here" as recited in claim 3 means. What is the 9-cell model that is illustrated in the claim? Applicant has not described this 9-cell model in claim 1, and thus this lacks proper antecedent basis.

(G) As per claim 4, it is unclear how the system is applied when a patient's medical conditions are entered. How are a patient's medical conditions entered so that the system is applied? If the system populates specific data fields, it is suggested Applicant positively recite this limitation as performed by the system.

(H) Claim 8 recites "the SOOMM system could be written within a broader program such as an electronic medical record designed by another group." How is the system written as part of an electronic medical record? What is a broader program? It would

appear that an SOOMM system could be incorporated into a software system for maintaining electronic medical records. The Examiner requests clarification.

(I) Claims 10 and 11 recite that the SOOMM "can be applied to patients with multiple medical conditions, diagnoses, and concomitant medications" and "can use, for medical conditions, laboratory, or other subjective data that defines a medical condition rather than having that stated only in a problem list."

It is noted that a recitation of the intended use of the claimed invention, namely the SOOMM "can be applied to patients with multiple medical conditions, diagnoses, and concomitant medications" and "can use, for medical conditions, laboratory, or other subjective data that defines a medical condition rather than having that stated only in a problem list," must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

(J) Claim 12 currently recites "the SOOMM system is fundamentally different than an inference engine, neural network or those less rigorous and predictable such as "fuzzy logic" that employ random or statistical probabilities rather than rigorous protocols." It is unclear to the Examiner what type of system the Applicant intends to claim with the

presently recited system that is not comprised of an inference engine, neural network, or fuzzy logic. It is respectfully submitted that such a limitation is tantamount to a negative limitation, which attempts to define the system in terms of what it is not, rather than what it is. As such, the scope of the claim cannot be ascertained.

(K) Claim 13 recites any computer programming language, "either existing or future developed, that can express the concepts described." It is unclear what programming languages will be developed in the future or what programming languages express the concepts described. What are the "concepts described" in claim 13 or independent claim 1? As such, the scope of the claim cannot be ascertained.

(L) Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. It is unclear what operating systems would not support a programming language and what operating systems would support a programming language.

(M) Claim 15 recites rules may reflect "the accepted knowledge of the day." What is the accepted knowledge of the day? It is unclear what the scope of claim 15 is because it is unclear what the accepted knowledge of the day would be.

(N) Claims 17 and 18 recite pharmaceutical and non-pharmaceutical treatments that exist "or are not discovered, invented, or patented" and any disease and medical

conditions that exist or "may be discovered in the future." What are treatments that are not discovered, invented, or patented and what conditions may be discovered in the future? It is unclear what the scope of claims 17 and 18 are because it is unclear what these terms mean.

13. Because claims 1-20 are so indefinite, no art rejection is warranted as substantial guesswork would be involved in determining the scope and content of these claims. See *In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962); *Ex parte Brummer*, 12 USPQ 2d, 1653, 1655 (BPAI 1989); and also *In re Wilson*, 424 F.2d 1382, 165 USPQ 494 (CCPA 1970). Prior art pertinent to the disclosed invention is nevertheless cited and applicants are reminded they must consider all cited art under Rule 111(c) when amending the claims to conform with 35 U.S.C. 112.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches:

US PATENTS

US 5594637	System and method for assessing medical risk
US 6128620	Medical database for litigation
US 6334192	Computer system and method for a self administered risk assessment
US 6458080	Managing parameters effecting the comprehensive health of a user
US 6529892	Apparatus, method and product for multi-attribute drug comparison
US 6789091	Method and system for web-based analysis of drug adverse effects
US 6804661	Drug profiling apparatus and method
US 6826541	Methods, systems, and computer program products for facilitating user choices among complex alternatives using conjoint analysis

US-PGPUBS

US 2001/0056359	System and method for communicating product recall information, product warnings or other product-related information to users of products
US 2002/0077549	Systems and methods for screening for adverse effects of a treatment
US 2002/0156651	Prescription system for unregulated therapeutic substances
US 2002/0165762	Method for integrated analysis of safety, efficacy and business aspects of drugs undergoing development
US 2002/0165845	Method and system for web-based analysis of drug adverse effects
US 2002/0183965	Method for analyzing drug adverse effects employing multivariate statistical analysis
US 2003/0088365	System and method of drug development for selective drug use with individual, treatment responsive patients, and applications of the method in medical care
US 2003/0135128	Electroencephalography based systems and methods for selecting therapies and predicting outcomes
US 2003/0158755	System and method for conducting drug use evaluation
US 2003/0191670	Medication compatibility profile data system
US 2004/0117126	Assessment and management of risks associated with utilizing pharmaceutical product, by conducting logical hazard assessment of failure modes, and designing risk management intervention program to manage adverse events
US 2004/0143346	Handheld medication dosage calculator
US 2005/0124863	Drug profiling apparatus and method

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (571) 272-6767. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (571) 272-6776.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

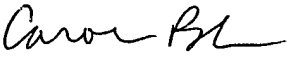
16. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(571) 273-8300	[Official communications]
(571) 273-8300	[After Final communications labeled "Box AF"]
(571) 273-6767	[Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to the Knox Building, Alexandria, VA.



Carolyn M. Bleck
Patent Examiner
Art Unit 3626